interviews with relevant stakeholders, questions about the target patient population, the intervention and standard care could be answered. Some issues arose such as variation in standard care and the definition of risk categories. Evidence on the prognostic value of some biomarkers was also found to be inconsistent. Decision-analytic modelling could be applied to synthesize all available evidence and estimate the health benefits and costs of the intervention and standard care options. The influence of the diagnostic accuracy of the test and assumptions about the patient population and treatment outcomes could be evaluated. Not all questions regarding the generalizability of the results to other settings could be answered by these techniques. **CONCLUSIONS:** The role of early HTA for companion diagnostics is to identify the gaps in evidence on the clinical and economic value of biomarkers, variation in standard care, and key stakeholders and their preferences. This information is necessary for forecasting the issues that will be encountered when positioning a pharmacogenomic test in the market.

PRM178

EXCEL TO MOBILE: THE METHOD FOR AUTOMATED MIGRATION OF EXCEL-BASED MARKOV MODELS TO MODERN SOFTWARE PLATFORMS

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The objective is to automate the migration of complex health economics Excel models based on Markov chains to modern software platforms, such as Mobile or Web. In this research project, we have developed a software solution that is capable of transforming a Microsoft Excel model into a self-contained platform-independent programming module. This module fully preserves the original model along with cell values, formulas and dependencies, and is capable of running the model independently from the Microsoft Excel environment. The module is used as a basis for creating web and mobile applications supporting calculations identical to that in Excel model. These applications will give the user means to manipulate model inputs and see the results of his actions immediately without having the full model delivered, thus preserving the confidentiality of proprietary data and algorithms. By using our method, several Excel based Markov cohort models with more than 1000 cycles were transformed and used as a basis for development of web-based and iPad applications for health care decision making. These applications showed performance comparable to Microsoft Excel and complete outcomes correlation with the original model. With the proposed solution, mature Excel models developed over the years in various institutions can be connected with modern information technologies in a fast and reliable way. Our method makes automated model transformation possible without human intrusion into a stable model core. By eliminating the dependency on Microsoft Excel, we open new ways for integration of time-proven Excel models with modern software platforms, such as the Web or Mobile.

DISEASE-SPECIFIC STUDIES

DIABETES/ENDOCRINE DISORDERS - Clinical Outcomes Studies

PDB1

REAL-WORLD INCIDENCE OF HYPOGLYCEMIA AND ASSOCIATED COSTS AMONG INSULIN GLARGINE-TREATED PATIENTS WITH TYPE 2 DIABETES MELLITUS (T2DM)

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OBJECTIVES: To identify real-world incidence and related costs of hypoglycemia among T2DM patients initiating insulin glargine (GLA). **METHODS:** Patient-level data from 6 published observational retrospective studies using health plan claim databases were pooled. Included were T2DM patients with continuous health plan coverage for 6 months before and 1 year after initiation, who were previously on oral antidiabetic drugs (OADs) or glucagon-like peptide-1 (GLP-1) analogs and initiated GLA (2007-2009) via disposable pen (GLA-P) or vial/syringe (GLA-V). In each study, observed differences between the two cohorts were removed by propensity score matching. Hypoglycemia and associated health care costs were measured over a 1-year follow-up period. **RESULTS:** Included were 14,911 GLA-P patients and 8,187 GLA-V patients (age 54.1 years, 53.5% men, mean Charlson Comorbidity Index 0.55, # of OADs 2.45, A1C 9.34% where available). During follow-up, prevalence rates of any hypoglycemia and inpatient/emergency room (ER)-related hypoglycemia were low overall, particularly for GLA-P (5.49% vs 7.70% and 1.60% vs 3.26%; both $P<0.0001$). Incidence rates of any hypoglycemia and inpatient/ER-related hypoglycemia were 25.7 and 3.8 events/100 patient years, and lower for GLA-P (any: 20.4 vs 35.5 events/100 patient years; ER-related: 2.6 vs 6.1 events/100 patient years; both $P<0.0001$). Hypoglycemia-related costs were lower for GLA-P ($225 vs $417; $P=0.001$). Hypoglycemia-related costs contributed 0.75% of overall health care costs and 1.5% of diabetes-related health care costs across both cohorts; in the GLA-P cohort the contribution was 0.55% and 1.07% (both $P<0.001$) of overall and diabetes-related costs, respectively. A1C reduction from baseline ($N=1,896$) was larger for GLA-P (-1.22% vs -0.86%, $P=0.0012$), and correlated with higher incidence of hypoglycemia ($r=-0.151$; $P<0.0001$). **CONCLUSIONS:** Patients initiating insulin glargine treatment showed low rates of hypoglycemia, especially when using a disposable pen device. Hypoglycemia-related costs were low, contributing a very small proportion to overall and diabetes-related health care costs.

PDB2

SYSTEMATIC LITERATURE REVIEW OF THE EFFICACY AND SAFETY OF METFORMIN EXTENDED RELEASE RELATIVE TO METFORMIN IMMEDIATE RELEASE IN THE TREATMENT OF TYPE 2 DIABETES MELLITUS

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OBJECTIVES: The use of standard immediate release metformin (MIR) two or three times daily has been associated with gastrointestinal adverse events (GIAE). Metformin XR (MXR) is a once a day extended release formulation that offers a potential benefit of a decrease in the frequency of GIAE and increased adherence rates in patients diagnosed with Type 2 Diabetes Mellitus (T2DM). This systematic review identifies published evidence regarding the efficacy, safety, and adherence of MXR relative to MIR in the treatment of T2DM. **METHODS:** We searched relevant bibliographic databases, internet and grey literature, and included all studies with an analytical or observational design. We assessed the quality of all selected studies following the Cochrane Collaboration recommendations. When possible, we calculated the mean global effect of MXR vs. MIR for clinical outcomes. **RESULTS:** The search identified 81 studies of which 10 met inclusion/exclusion criteria for analysis. The quality of these 10 studies was generally poor. Efficacy results of 187 patients were included in a meta-analysis that estimated the mean difference with respect to baseline measurements. Glycosylated hemoglobin (HbA1c) control, fasting plasma glucose and lipid control was similar in both treatments ($MD=0.01$ CI95%=-0.38-0.41; $MD=0.32$ CI95%=-0.25-0.89; $MD=0.16$ CI95%=-0.23-0.54, respectively). The frequency of GIAE was meta-analyzed using data from 1,045 patients, and the global Relative Risk was estimated ($RR=0.97$; CI95%=0.80-1.19). Patients treated with MXR experienced a significantly lower incidence of nausea ($RR=0.82$; CI95%=0.46-1.95) and dyspepsia ($RR=0.64$; CI95%=0.29-1.43) than patients on MIR. Adherence was reported in two studies, showing that patients treated with MXR have a significantly higher adherence to treatment than MIR cohorts. **CONCLUSIONS:** Treatment once a day with MXR tablets has comparable efficacy to a two or three times daily dosage with MIR. MXR offers the benefit of increased adherence to treatment, and a lower frequency of nausea and dyspepsia compared to MIR.

PDB3

HOW DIFFERENT WERE THEY? A TREATMENT PATTERN ANALYSIS OF UNITED STATES PATIENTS WITH TYPE 2 DIABETES MELLITUS (T2DM) INITIATING INJECTABLE THERAPY

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OBJECTIVES: The Initiation of New Injectable Treatment Introduced after Antidiabetic Therapy with Oral-only Regimens (INITIATOR) study aims to investigate real-world outcomes among T2DM patients failing oral antidiabetic drugs (OADs) and initiating injectable therapy with insulin glargine (GLA-P) or the glucagon-like peptide 1 analog liraglutide (LIRA). This analysis reports treatment pattern data from the pilot retrospective study phase of INITIATOR. **METHODS:** Two independent administrative claims databases from OptumInsight™ (OI) and HealthCore® (HC) were assessed retrospectively. Data were included from adult T2DM patients previously on OADs only, initiating GLA-P or LIRA injectable therapy (January–July 2010) with continuous health care coverage during the 6 months before (baseline), and 9 (OI) or 12 months (HC) after initiation (follow-up). Baseline characteristics, treatment patterns, and outcomes among GLA-P and LIRA cohorts were assessed descriptively. **RESULTS:** 2,684 patients were included (OI: GLA-P n=610, LIRA n=365; HC: GLA-P n=1,188, LIRA n=521). Compared to LIRA patients, GLA-P initiators were older (56 years vs 53 years; $P<0.001$), less obese (9.2%-12% vs 18%-19%; OI: $P=0.01$, HC: $P<0.001$), had higher comorbidity (CCI 1.1-1.2 vs 0.6-0.7; $P<0.001$) and higher A1C (9.1%-9.7% vs 7.7%-7.9%; $P<0.001$), and were much less likely to have baseline A1C <7.0% (9%-11% vs 30%-34%; $P<0.001$).During follow-up, the 9-month (OI) treatment persistence rate was 63.1% for GLA-P and 52.1% for LIRA; the 12-month (HC) rate was 60.2% for GLA-P and 50.9% for LIRA. Total annualized all-cause health care costs for GLA-P vs LIRA, respectively, were $16,560 vs $14,984 (OI), and $16,466 vs $14,579 (HC). Study drugs contributed 7% (GLA-P) and 17%-19% (LIRA) to the total costs. **CONCLUSIONS:** GLA-P and LIRA are prescribed to very different T2DM patients in a real-world setting, with about 1/3 of LIRA initiators characterized by baseline A1C < 7.0%. These differences in patient characteristics need to be taken into account when conducting related comparative effectiveness research.

PDB4

HBA1C REDUCTION ASSOCIATED WITH INITIAL VERSUS SEQUENTIAL COMBINATION THERAPY WITH PIOGLITAZONE (PIO) AND DIPEPTIDYL PEPTIDASE-4 INHIBITORS (DPP4I) IN PATIENTS WITH TYPE 2 DIABETES MELLITUS (T2DM)

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OBJECTIVES: For the management of T2DM using combination therapy with PIO and DPP4i, there is no consensus on whether to initiate both drugs simultaneously or start with PIO followed by sequential addition of DPP4i. We aimed to assess impact of initial vs. sequential combination therapy with PIO and DPP4i on HbA1C reduction. **METHODS:** A chart review was conducted among people with T2DM to